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| APPLICATION NO.                                  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |  |
|--|-------------|----------------------|---------------------|-----------------|--|
| 10/716,625                                       | 11/20/2003  | Nurith Shaklai       | 3239/3 6348         |                 |  |
| 7590 10/24/2006                                  |             |                      | EXAM                | EXAMINER        |  |
| DR. MARK FRIEDMAN, LTD.<br>C/O DISCOVEY DISPATCH |             |                      | SAUCIER, SANDRA E   |                 |  |
| 9003 FLORIN WAY                                  |             |                      | ART UNIT            | PAPER NUMBER    |  |
| UPPER MARLBORO, MD 20772                         |             | 1651                 |                     |                 |  |

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.   | Applicant(s)   |  |  |  |  |
|---|---|--|--|--|--|--|
| Office Astice Comments  | 10/716,625  | SHAKLAI ET AL.   |  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit   |  |  |  |  |
|   | Sandra Saucier  | 1651   |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |   |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | J. nely filed the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |  |
| Status  |   |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 14 Se  | eptember 2006.  |  |  |  |  |  |
| ·_ ·  |   |  |  |  |  |  |
| 3) Since this application is in condition for allowar   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is   |  |  |  |  |  |
| closed in accordance with the practice under E  | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.   |  |  |  |  |  |
| Disposition of Claims   |   |  |  |  |  |  |
| 4)⊠ Claim(s) <u>41-54</u> is/are pending in the application.  |   |  |  |  |  |  |
| 4a) Of the above claim(s) 48 and 49 is/are withdrawn from consideration.  |   |  |  |  |  |  |
| 5) Claim(s) is/are allowed.   |   |  |  |  |  |  |
| 6)⊠ Claim(s) <u>41-47 and 50-54</u> is/are rejected.  |   |  |  |  |  |  |
| 7) Claim(s) is/are objected to.   |   |  |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.   |   |  |  |  |  |  |
| Application Papers  | V.  |  |  |  |  |  |
| 9) The specification is objected to by the Examiner.  |   |  |  |  |  |  |
| 10)⊠ The drawing(s) filed on <u>11/20/03, Figure 11A, B, C</u> is/are: a) accepted or b)⊠ objected to by the Examiner.  |   |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |   |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |  |  |  |  |  |
| Priority under 35 U.S.C. § 119  |   |  |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul> |   |  |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  | 4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal Pa   | te   |  |  |  |  |

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### **DETAILED ACTION**

Claims 41-54 are pending. Claims 41-47, 50-54 are considered on the merits. Claims 48-49 are withdrawn from consideration as being drawn to a non-elected invention.

### Election/Restriction

Applicant's election with traverse of the species, platelets in the reply filed on 9/14/06 is acknowledged. The traversal is on the ground that the species are not mutually exclusive, but does not explain how a platelet is not mutually exclusive from a stem cell, for example. This is not found persuasive because various fractions of blood which are termed blood products are clearly distinct. If applicant will accept a reference making claims directed to "platelets" anticipated or obvious as making claims directed to all blood products such as stem cells anticipated or obvious, on the record, the examiner will remove the election of species requirement. Applicant further argues that a simultaneous search of all species can be made without undue burden. However, the applicant does not explain how a search of the term "platelet" would encompass "stem cells" or "plasma" for example. Burden is found especially in the search of non-patent literature where text searching is performed. The requirement is still deemed proper and is therefore made FINAL.

## Priority

Please request a corrected priority data sheet as the PCT document is missing from the continuing data information as recorded in PALM.

## Claim Rejections - 35 USC § 112

### **INDEFINITE**

Claims 46 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Method steps should be in active voice. Storing... instead of "is stored".

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It is uncertain if applicant intends to add further steps to the method.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 41, 42, 44-47, 50-54 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 5,476,764 [A].

The claims are directed to a method comprising treating a blood product with CO. The elected species is platelets. With regard to claims 53 and 54, these are optional ingredients.

US 5,476,764 discloses introducing CO into a blood product, red cells. Although the elected species is platelets, the above reference demonstrates that the generic claim is not allowable.

Claims 41 and 42 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Amersi *et al.* [U].

Amersi *et al.* disclose treating whole blood with 300ppm CO (page 816, Experimental Design). The above reference demonstrates that the generic claim is not allowable.

Claims 41-47, 53, 54 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Brune *et al.* [V].

Brune *et al.* disclose a method of gassing PRP or washed platelets resuspended in a bicarbonate buffer with pure CO (Materials and Methods).

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Claims 50-52 appear to be directed to allowable subject matter if limited to platelets.

#### Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sandra Saucier

Primary Examiner

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October 18, 2006